

**K061557 FUSION**Sep 15, 2006  
102 days to decisionK061557 · Product code: **DXN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k061557/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jun 5, 2006
Decision date	Sep 15, 2006
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medwave, Inc.</b>
Location	St. Paul, MN, US
Contact	DONNA R LUNAK
510(k) history	5 submissions · 5 cleared · 1995-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061557/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026